REMARKS

The claim amendments and remarks herein are responsive to the Final Office Action dated February 14, 2006. Applicant has amended Claims 1, 21, and 44.

Claim Objections

The Examiner objected to Claims 1-3, 6, 21-22, 44-47, and 65. According to the Examiner, the term "anulus" should be spelled "annulus". Applicant respectfully disagrees with the Examiner. For example, Applicant directs the Examiner's attention to the American Journal of Neuroradiology, which in its glossary states:

"Either anulus or annulus is correct spelling."

See http://www.asnr.org/spine_nomenclature/glossary.shtml, attached herewith as Appendix A.[1] Further, the term "anulus" in the claims is consistent with the spelling throughout the specification of this application.

Accordingly, Applicant respectfully requests that the Examiner withdraw the objection.

Claim Rejections

Rejection under 35 U.S.C. § 101

The Examiner rejected Claims 1-8, 11, 44-47, 62, and 64 under 35 U.S.C. § 101. Applicant respectfully asserts that Claims 1-8, 11, 44-47, 62, and 64 comply with 35 U.S.C. § 101.

Claims 1 is directed to encapsulating nuclear augmentation material, which is provided in combination with at least one anulus augmentation device. Thus, the combination is non-naturally occurring and thus patentable under 35 U.S.C. § 101.

Likewise, Claim 44, which recites "at least one anchor is adapted to be coupled to at least a portion of the anulus augmentation device" is directed to a non-naturally occurring combination of an anulus augmentation device and nucleus augmentation material.

[1] Applicant relies on this glossary only to show that the term "anulus" is spelled correctly, and not for any other purpose.

Claim 21 also recites a non-naturally occurring combination of an anulus augmentation device and nuclear augmentation material.

Further, the nuclear augmentation material recited in Independent Claims 1 and 21 are materials to augment the nucleus. These materials include, for example, polyurethane, polyester, PEEK, PET, FEP, PTFE, ePTFE, PMMA, nylon, carbon fiber, DELRIN (acetal), polyvinyl alcohol gels, etc.

Moreover, the augmentation materials in some embodiments, even if derived from a human, are first removed from the human, and then used as an augmentation material. It is well established that products found in nature are patentable if they have been given a new form, quality, property or combination not present in the original article (e.g., the human) existing in nature. Here, the materials in some embodiments are isolated from a human, and then used to augment the nucleus.

Accordingly, Applicant respectfully respects that the Examiner withdraw the rejection of Claims 1-8, 11, 44-47, 62, and 64 under 35 U.S.C. § 101. Applicant expressly reserves its right to argue this issue on appeal.

Rejection under 35 U.S.C. § 112

The Examiner rejected Claims 1-8, 11, 44-47, 62, and 64-66 under 35 U.S.C. § 112. Although Applicant respectfully maintains that the previously pending claims are supported by the specification, Applicant has amended Claims 1 and 21 to recite a nuclear augmentation material that comprises a fluid that is adapted to remain fluid after said nuclear augmentation material is implanted or infused in an intervertebral disc.

Applicant's language complies with both the written description and enablement requirement. Applicant's specification [page 50, ¶¶ 233-4] expressly provides, inter alia:

> The augmentation material 554 may remain "fluid" after the infusion step, or may polymerize, cure, or otherwise harden to a less flowable or nonflowable state.
>
> ***
>
> Additional additives and components of the nucleus augmentation material are recited below. In general, the nature of the material 554 may remain constant during the deployment and post-deployment stages or

may change, from a first infusion state to a second, subsequent implanted state.

Indeed, the Examiner has recognized that Applicant's disclosed material "may remain fluid after the infusion step." OA at page 2. The claims which depend from Claim 1 or Claim 21 are also compliant with 35 U.S.C. § 112.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of the claims under 35 U.S.C. § 112.

CONCLUSION

If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below. No fees are believed due. However, please charge any fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: August 14, 2006 By: _____

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APPENDIX A

<http://www.asnr.org/spine_nomenclature/glossary.shtml>.
Selected page from the AJNR showing that the spelling of "anulus" is correct.

AJNR

Nomenclature and Classification of Lumbar Disc Pathology

GLOSSARY

Note: Some terms and definitions included in this Glossary are not recommended as preferred terminology, but are included to facilitate interpretation of vernacular and, in some cases, improper use. Preferred definitions are listed first. Confusing or inaccurate alternative definitions are placed in brackets and designated as "Non-Standard."

aging disc: Disc demonstrating the features of normal aging. Spondylosis deformans possibly represents the normal aging process.

anterior displacement: Displacement of disc tissues beyond the disc space into the anterior zone.

anterior zone: Peridiscal zone that is anterior to the mid-coronal plane of the vertebral body.

anulus, annulus (abbreviated form of annulus fibrosus): A multilaminated ligament surrounding the periphery of each disc space, attaching, cranial and caudad, to end-plate cartilage and ring apophyseal bone and blending centrally with nucleus pulposus. Note: Either anulus or annulus is correct spelling. Nomina Anatomica uses both forms whereas Terminologia Anatomica states "anulus fibrosus." [8,21] Fibrosus, has no correct alternative spelling; fibrosis has a different meaning and is incorrect in this context.

asymmetric bulge: Presence of outer anulus beyond the plane of the disc space, more evident in one section of the periphery of the disc than another, but not sufficiently focal to be characterized as a protrusion. Note: Asymmetric bulge is a morphologic observation of various potential causes and is not a diagnosis. See: bulge.

balloon disc (colloquial): Diffuse displacement of nucleus through the vertebral end plate, commonly seen in severe osteoporosis.

base (of displaced disc): The cross sectional area of disc material at the outer margin of the disc space of origin, where disc material displaced beyond the disc space is continuous with disc material within the disc space. In the cranio-caudal direction, the length of the base cannot exceed, by definition, the height of the intervertebral space.

broad-based protrusion: Herniation of disc material extending beyond the outer edges of the vertebral body apophyses over an area greater than 25% (90 degrees) and less than 50% (180 degrees) of the circumference of the disc. See protrusion. Note: Broad based protrusion refers only to discs in which disc material has displaced in association with localized disruption of the anulus and not to generalized (over 50% or 180 degrees) apparent extension of disc tissues beyond the edges of the apophyses. If the base is less than 25%, it is called "focal protrusion." Apparent extension of disc material, formation of additional connective tissue between osteophytes, or overlapping of non-disrupted tissue beyond the edges of the apophyses of over 50% of the circumference of the disc may be described as bulging. See: bulging disc, focal protrusion.